BILLING CODE: 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Methods of Analyzing Virus-Derived Therapeutics

Description of Technology:

Researchers at the National Cancer Institute's Biopharmaceutical Development Program recently developed massively parallel sequencing methods for virus-derived therapeutics such as viral vaccines and oncolytic immunotherapies. The methods allow for the determination of micro-heterogeneity and quantitation of low frequency sequence variants, which have the possibility of supplanting monkey neurovirulence safety testing (MNVT), mutant analysis by PCR, and restriction enzyme cleavage (MAPREC) methods that are currently used to screen RNA virus-derived therapeutics.

Potential Commercial Applications:

- Improved methods for detecting mutations in GMP-manufactured virus-derived therapeutics, including viruses, viral template plasmids, or vaccines;
- The method allows for at least two different virus-derived therapeutics to be assayed simultaneously.

Value Proposition:

- Provides a cost- and time-effective means of assaying a virus-derived therapeutic, such as oncolytic viruses, for viral sequence variants, for regulatory approval;
- RNA virus preparation steps increase the amount of viral RNA obtained;

- Demonstrated superiority of massively parallel sequencing ("MPS") over mutant analysis by PCR and restriction enzyme cleavage ("MAPREC") analysis.

Development Stage:

Clinical Phase I

Inventor(s):

Trevor Broadt (NCI), Michael D. Harwich (American International Biotechnology, LLC), William T. Budd (American International Biotechnology, LLC), Gregory A. Myers (American International Biotechnology, LLC)

Intellectual Property:

HHS Ref. No. E-240-2015/0-US-01, corresponding to US Provisional Patent App. No. 62/199,663, filed July 31, 201562/173,777, entitled "Methods of Analysis of RNA Virus-Derived Therapeutics"

HHS Ref. No. E-240-2015/0-PCT-02, corresponding to International Patent App. No. PCT/US2016/044788, filed July 29, 2016, entitled "Methods of Analyzing Virus-Derived Therapeutics"

Related Technologies: HHS Reference #E-267-2014/0 entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions".

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: August 16, 2016

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John D. Hewes

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